received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: William Burkholder, Center for Veterinary Medicine (HFV–229), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–5900, *william.burkholder@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 13, 2020 (85 FR 8297), FDA published the notice of availability for a draft guidance entitled ''Pre-Submission Consultation Process for Animal Food Additive Petitions or Generally Recognized as Safe (GRAS) Notices,'' giving interested persons until April 13, 2020, to comment on the draft guidance.

FDA received two comments on the draft guidance and those comments were considered as the guidance was finalized. Editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated February 2020.

This guidance provides uniform, consistent process information to industry to facilitate effective and efficient review of pre-consultation submissions for animal food additive petitions or GRAS substances and preparation of food use authorization requests.

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on the pre-submission consultation process for animal food additive petitions or GRAS notices for intended use in animal food. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance.

The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR 570.17 and 571.1 have been approved under OMB control number 0910–0546; the collections of information under 21 CFR part 570, subpart E have been approved under OMB control number 0910–0342; and the collections of information under 21 CFR part 58 have been approved under OMB control number 0910–0119.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: December 7, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–27256 Filed 12–10–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request Information Collection Request Title: Standardized Work Plan Form for Use with Applications to the Bureau of Health Workforce Research and Training Grants and Cooperative Agreements OMB No. 0906–0049—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR have been provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30 day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than January 11, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

A 60-day **Federal Register** Notice was published in the **Federal Register** on September 15, 2020, Vol. 85, No. 179, pp.57221–57222. There were no public comments.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Standardized Work Plan Form for Use with Applications to the Bureau of Health Workforce Research and Training Grants and Cooperative Agreements, OMB No. 0906–0049—Revision

Abstract: HRSA's Bureau of Health Workforce requires applicants of training and research grants and cooperative agreements to submit work plans via the Standardized Work Plan (SWP) form.

The information in the SWP describes the timeframes and progress required during the grant period of performance to address each of the needs detailed in the Purpose and Need section of the application, as required in the Notice of Funding Opportunity announcement.

Applicants use the SWP form when they submit their proposals, and award recipients and Project Officers use the SWP information to assist in monitoring progress once HRSA makes the awards. HRSA proposes a revision to the SWP to include a Quarterly Progress Update (QPU) for award recipients to provide information to HRSA on a quarterly basis on each activity listed in the SWP.

Need and Proposed Use of the Information: The information collected by the SWP form standardizes and streamlines the data used by HRSA in reviewing applications and monitoring awardees. The form asks applicants to provide a description of the activities or steps the applicant will take to achieve

each of the objectives proposed during the entire period of performance. The current standardized format and data submission by applicants increases efficiency in reviewing, awarding, and monitoring each project.

This revision to the clearance package will incorporate an additional form for participants, the QPU. The QPU is completed via HRSA's Electronic Handbook and prompts recipients to report on progress of activities that were submitted using the SWP in the original application. The QPU will automatically populate activities from the recipient's SWP form on a quarterly basis. For each activity listed in the submitted SWP for any particular quarter within the project period, recipients will select and submit a single selection response for each activity status from a pull-down menu with five options: Activity is on Schedule, Activity is Complete, Timing is off track, Activity will be missed if action is not taken, and Activity cannot be achieved. Information provided will be utilized by the program staff to regularly assess overall progress of program requirements and analyze data in order to monitor award recipient compliance and track progress against proposed targets and goals. Information gathered will allow for an improved and more efficient method for identifying whether projects' goals are being advanced or achieved, as set forth in 45 CFR 75.342. Program staff will also use information provided over the period of performance to see emerging trends and to assess whether an award recipient requires technical assistance to address challenges that the award recipient may be experiencing with the implementation of the project. Seeking OMB approval comports with the regulatory requirement imposed by 45 CFR 75.206(a), Paperwork clearances.

Likely Respondents: Recipients of HRSA Bureau of Health Workforce's research and training grants and cooperative agreements.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total annual burden hours
Standardized Work Plan (SWP)	1,000	1	1,000	1.00	1,000
Quarterly Progress Update (QPU) Form	1,000	4	4,000	.10	400
Total	[1] 1,000	–	5,000	–	1,400

[1] The 1,000 Standardized Work Plan (SWP) respondents reflects the number of new grant applications submitted annually. The 1,000 Quarterly Progress Update (QPU) respondents reflects the current volume of funded, active grants.

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2020–27318 Filed 12–10–20; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Research Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Findings of research misconduct have been made against Charles A. Downs (Respondent), former Adjunct Assistant Professor, Arizona Health Sciences Center, University of Arizona (UA). Respondent engaged in research misconduct in research supported by U.S. Public Health Service (PHS) funds, specifically National Center for Advancing Translation Sciences (NCATS), National Institutes of Health (NIH), grant UL1 TR000454. The administrative actions, including supervision for a period of four (4) years, were implemented beginning on November 18, 2020, and are detailed below.

FOR FURTHER INFORMATION CONTACT: Elisabeth A. Handley, Director, Office of Research Integrity, 1101 Wootton Parkway, Suite 240, Rockville, MD 20852, (240) 453–8200.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the Office of Research Integrity (ORI) has taken final action in the following case:

Charles A. Downs, University of Arizona: Based on the report of an investigation conducted by UA and analysis conducted by ORI in its oversight review, ORI found that Respondent, former Adjunct Assistant Professor, Arizona Health Sciences Center, UA, engaged in research misconduct in research supported by PHS funds, specifically NCATS, NIH, grant UL1 TR000454.

Respondent neither admits nor denies ORI's findings of research misconduct. Respondent and ORI desire to close this matter without further expense of time and other resources and thus have entered into a Voluntary Settlement Agreement (Agreement).

ORI found that Respondent engaged in research misconduct by intentionally, knowingly, or recklessly falsifying and/or fabricating data included in the following six (6) grant applications submitted for PHS funds:

- R01 NR016242–01, submitted to the National Institute of Nursing Research (NINR), NIH
- R01 NR016242–01A1, submitted to NINR, NIH
- R01 NR016957–01, submitted to NINR, NIH
- R01 NR016957–01A1, submitted to NINR, NIH